REMARKS UNDER 37 CFR § 1.116

Formal Matters

Claims 123-130 are pending after entry of the amendments set forth herein.

Claims 13, 15-21, 23-29, 31-37, 39-45, 47-53, 55-61, 63-69, 71-77, 79-85, 87-122 were examined and rejected. No claims were allowed.

New claims 123-130 are added to more distinctly claim the invention. Support for new claims is found in the previously pending, now canceled claims and throughout the specification, particularly at: page 2 line 34 to page 3 line 5, page 4 line 34 to page 5 line 6, and page 5, lines 19 to 24.

Claims 13, 15-21, 23-29, 31-37, 39-45, 47-53, 55-61, 63-69, 71-77, 79-85, 87-122 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue subject matter encompassed by all or any of the canceled claims not pursued in this application in one or more continuing applications.

The attached page captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE" shows the amendments made herein.

No new matter has been added by the new claims. Accordingly, their entry by the Examiner is respectfully requested.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

The Response in General

Applicants have provided a written description of an enabling disclosure of what they are claiming. Specifically, there is a written description of 150 contiguous nucleotides of SEQ ID NO:972. If others do no make, sell or use a polynucleotide that has at least 150 contiguous nucleotides (or the complement thereof) of SEQ ID NO:972, then the claim does not literally cover such a sequence. The presence of additional nucleotides is not relevant to the issue of written description, enablement or infringement. This simple point overcome the rejections. To the extent a further discussion is believed necessary, the Examiner is respectfully referred to the following.

The Law of Written Description

35 U.S.C §112, ¶ 1 requires that the specification shall contain a written description of the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

As interpreted by the court in *Vas-Cath*, this "written description" requirement of the statute demands that an application "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". [1] In determining whether the specification meets the written description requirement for the invention now claimed, "[t]he primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure."[2] (emphasis added) As such, a proper assessment of whether the instant patent application (Serial No. 09/313,292; the '292 specification) provides an adequate written description of the invention of claims 123-130 must include a determination of the relevant facts and an assessment of whether the '292 specification would have provided sufficient description of the invention to allow a Skilled Person to conclude that the Inventors were in possession of the invention.

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[1] *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-1564 (Fed. Cir. 1991).
[2] *In re Wertheim*, 191 U.S.P.Q. 90, 96 (C.C.P.A. 1996).

Applicants now turn to the case at hand.[3]

As noted above, when determining if a specification satisfies the written description requirement for the claimed invention, "[t]he primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure."[4] To this end, applicants provide herewith the Declaration of Dr. Christopher Somerville under 37 C.F.R. § 1.132. Dr. Somerville's Declaration is evidence of how a Skilled Person in May, 1999 would view the description of the claimed invention in the '292 specification.

Applicants note that the law requires the Office to consider this evidence as probative of how one skilled in the art would have understood the teachings of the '292 specification as it relates to claims 123-130.[5]

Dr. Somerville's declaration explains that one of ordinary skill in the art would recognize disclosure of SEQ ID NO:972 as fully representative of the genus of the claimed invention since it is a complete disclosure of the common structural feature (i.e., at least 150 contiguous nucleotides of SEQ ID NO:972) of the claimed invention. (Declaration paragraph 17). Furthermore, Dr. Somerville's declaration evidences that one of ordinary skill in the art would recognize that the vector containing a cDNA containing the sequence of SEQ ID NO:972 and deposited with the A.T.C.C. is an example of a polynucleotide containing SEQ ID NO:972 having flanking sequences and as being fully representative of large polynucleotides that can serve as probes or starting materials for probes in cancer diagnostics. (Declaration paragraph 17). In addition, Dr. Somerville states that a Skilled Worker could determine whether a given polynucleotide is encompassed by the claim.

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[3] In their arguments, Applicants have relied upon the disclosure of the '292 specification, which was filed in May, 1999. The instant application claims priority to a series of provisional patent applications. In basing their arguments upon the specification of the May 1999 filing applicants in no way suggest that the priority applications are not equally sufficient in their support and description of the claimed invention.

[4] *In re Wertheim*, 191 U.S.P.Q. 90, 96 (C.C.P.A. 1996).

As such, in Dr. Somerville's opinion, the '292 specification, when considered from the point of view of a Skilled Person, provides adequate written description of the invention of claims 123-130, and that the inventors indeed had possession of the invention of claims 123-130 as of the filing date of the '292 specification in May 1999.

Rejection under 35 U.S.C. §112, first paragraph

The rejection of claims 13, 15-21, 23-29, 31-37, 39-45, 47-53, 55-61, 63-69, 71-77, 79-85, 87-122 has been maintained for reasons of record in the first Office Action mailed December 1, 2000. This rejection is respectfully traversed as applied and as it may be applied to new claims 123-130.

Summary of the outstanding rejection

In the first Office Action (mailed December 1, 2000), the Office asserted that that claims 13-92 were "directed to full length cDNA, sequences that hybridize to [the recited SEQ ID NOS], sequences from other species, mutated sequences, allelic variants, and splice variants." The Office Action further asserted that with the exception of the specific SEQ ID NOS, the "skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation." In making the rejection, the Office cited *Amgen, Inc. v. Chugai Pharmaceutical Co.*, *Fiers v. Revel*, *Fiddes v. Baird*, and *University of California v. Eli Lilly and Co.*

In rebutting Applicants' arguments against the above-described rejection, the Office stated in the final Office Action mailed August 31, 2001:

> As there is no indication that the claimed SEQ ID NOS contain a complete open reading frame, the use of open language in the claims causes the claimed invention to read on at least a full open reading frame whose sequence is not described in the instant specification.

[5] *In re Alton*, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996)

This rejection is traversed as applied and as it might apply to claims 123-130.

The '292 specification provides an adequate written description of the invention recited in claims 123-130, and further shows that the inventors indeed had possession of the invention of claims 123-130 as of the filing date of the '292 specification in May 1999, as will be asserted below.

The Office uses an impermissible standard for written description

The first Office Action states, in paragraph 13, that "with the exception of SEQ ID NOS:730, 731....., the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation". The Office has used this statement as a basis for the written description rejection.[6]

The standard for written description has been established over several years of court cases such as *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 and *In re Wertheim* 191 USPQ 90, and has culminated in the publication of the "Written Description Guidelines" Federal Register Vol. 66 No. 4, dated January 5, 2001 to which the Office must adhere to when making a written description determination.

Applicants are not aware of any interpretation of the law of written description that uses, as a test, whether or not a skilled artisan can "envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation". As such, Applicants do not accept this assertion. The Examiner has not provided any factual evidence to support the rejection, and thus the statement with regard to what one of ordinary skill in the art would know must be based on the Examiner's personal knowledge. We hereby request an affidavit under 37 C.F.R. §1.104(d)(2) to support this assertion.

[6] Applicants note that the Office Action's arguments with respect to proteins is not relevant. The claims of the instant application are directed to polynucleotides, not proteins.

As stated above, the law requires that the specification shall contain a written description of the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. Dr Somerville, in his declaration, has stated that this standard would be met in the instant application.

The Office has impermissibly read a limitation into the claims

As noted above, in the first Office Action mailed December 1, 2000 the Office states, in paragraph 13, that "claims 13-92 *are directed to* full length cDNA..." [emphasis added], and, as such, the written description rejection issued in the first Office Action, the final Office Action (specifically section No. 6) mailed August 31, 2001, and the Advisory Action mailed April 25, 2002 is based on the reasoning that a full length cDNA is not described in the specification.

The instant claims are directed to a genus of polynucleotides, which polynucleotides contain an identifiable structural feature. The instant specification describes a vast variety of probes, vectors, and other longer DNA fragments containing the structure, only one of which is the full length cDNA.

Applicants clarify that although the claims may *encompass* full length cDNA, they are not *directed to* (i.e., limited to) full length cDNA. Applicants assert that the Office has impermissibly read into the claims a limitation that simply is not present.

The Office has impermissibly used lack of description of an individual single species to argue that a genus of species containing the single species is not described

The language of the Office Action indicates that the Office is impermissibly reading a limitation into the claims (i.e., that the claims are directed to full-length cDNAs), and then focusing upon whether the specification describes a cDNA having an open reading frame. Applicants submit that this is not proper.

Specifically, the Office Action states that "the use of open language in the claims causes the claimed invention to read on at least a full open reading frame whose sequence is not described in the instant specification" as a grounds for the rejection.

Applicants are not aware of any interpretation of the law of written description that requires that the specification identify a "full open reading frame." Even the "Synopsis of Application of Written Description Guidelines" (hereafter "Synopsis"; posted on the USPTO world wide website on March 1, 2000) does not support this assertion. The Synopsis states that "For example, a cDNA's principle attribute would include its coding region." (emphasis added)[7] Applicants again note that the claims are not so limited to cDNAs. Furthermore, the Synopsis is not stating that a coding region is the only attribute of a polynucleotide, but rather is an example of attributes, since these "include" a coding region.

As noted above, the claims are not so limited to cDNAs, but rather are directed to a genus of polynucleotides, all of which share the feature of "at least 150 contiguous nucleotides of SEQ ID NO:972". As previously argued, and as Dr. Somerville has opined, the instant specification has adequately described a vast variety of polynucleotides, for example probes, vectors, clones, restriction fragments and PCR products that contain at least 150 nucleotides of SEQ ID NO:972. The full length cDNA is merely one of many species encompassed within the claimed genus. It is not recited or referred to in any way by the claims, and there is no basis in fact or law for viewing that species as an essential or critical element.

The Office Action cites no basis in the law (nor are the applicants aware of any basis) for the proposition that a genus which is described in the specification nevertheless fails to meet the written description requirement because one single species is not disclosed. In fact, *In re Angstadt*[8] states that applicants' specification need not describe every possible species within a broadly claimed genus in order to satisfy the requirement of 35 U.S.C §112, first paragraph. As stated by the court in *In re Alton*, "If a person of ordinary skill in the art would have understood

[7] Synopsis of Application of Written Description Guidelines, page 31.
[8] 537 F.2d 498, 502-503 (CCPA 1976)[8]

the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met."[9]

In the field of recombinant DNA technology, making and using specific nucleic acid sequences routinely involves incorporating the sequences into larger molecules, including cloning and expression vectors and PCR products. Moreover, these specific nucleic acid sequences retain at least one utility, e.g., as probes for diagnosing cancers. The variety of useful larger molecules comprising a specific nucleic acid sequence is almost limitless. In this field, the practical reality is that larger nucleic acid molecules into which an inventive nucleic acid sequence can be inserted should be viewed as the functional milieu in which an inventive sequence can be made and used. In this context, inventors of nucleic acids would be deprived of meaningful patent protection if they were limited to claims directed to only the specific nucleic acid.

Here, the Office concludes that since the specification does not describe the sequence of the full-length open reading frame of a cDNA comprising SEQ ID NO:972, and the claims encompass such a sequence, the specification does not provide an adequate written description of the claimed invention. However, this is only a particular species of the genus of the claimed polynucleotides. The lack of written description of a single species is not sufficient to support a rejection of the claimed genus.

The claims are adequately described in the specification

The law requires that the specification shall contain a written description of the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

Dr Somerville states that one of ordinary skill in the art would recognize disclosure of SEQ ID NO:972 as fully representative of the genus of the claimed invention since it is a

[9] *In re Alton*, 76 F.3d 1168, 1177 (Fed. Cir. 1996).

complete disclosure of the common structural feature (i.e., at least 150 contiguous nucleotides of SEQ ID NO:972) of the claimed invention. (Declaration paragraph 17). Dr Somerville also states that one of ordinary skill in the art would recognize that the vector containing a cDNA containing the sequence of SEQ ID NO:972 and deposited with the A.T.C.C. is an example of a polynucleotide containing SEQ ID NO:972 having flanking sequences and as being fully representative of large polynucleotides that can serve as probes or starting materials for probes in cancer diagnostics. (Declaration paragraph 17). In addition, Dr. Somerville states that a Skilled Worker could determine whether a given polynucleotide is encompassed by the claim. (Declaration paragraph 45).

Dr. Somerville concludes, the specification provides sufficient written description of the characterizing details sufficient to distinguish the claimed genera of polynucleotides from all others. (Declaration paragraph 44) Thus, the genera of claimed polynucleotides are readily recognizable by one of ordinary skill in the art.

Dr. Somerville's Declaration indicates that the requirements for written description have been met, and, as such, the claims are adequately described in the instant specification. The Office must consider the Somerville Declaration and any rebuttal of the Somerville Declaration must articulate adequate reasons, and must consider the totality of the record in doing so.[10]

The skill level of one of ordinary skill in the art was dramatically higher in May of 1999, than in the cited cases

According to 35 U.S.C §112, ¶ 1, written description is analyzed from the point of view of one of skill in the art at the time of filing.

In his declaration, Dr. Somerville concludes that since the field of recombinant DNA technology is a rapidly evolving, and most major technological advances have been made in the last 20 years (e.g. computer programs for comparing nucleic acids), a Skilled Person had a dramatically higher skill level in May 1999 as compared to the filing dates of the applications at

issue in the cases that a were cited against the Applicants in the first Office Action (*i.e. Amgen Inc. v. Chugai Pharmaceutical Co., Fiers v. Revel, Fiddes v. Baird, and University of California v. Eli Lilly and Co*). (Declaration paragraph 47)

Because of the advances in the art, Dr. Somerville states that he does not believe that a statement regarding what one of ordinary skill can or cannot do in the above cases would be factually correct with respect to the Skilled Person in May of 1999. (Declaration paragraph 47)

In view of this evidence, Applicants submit that assertions of the ability of one of ordinary skill in the art based on the cited cases is not proper. As such, and further since the facts of the cited cases and the facts in the instant case differ dramatically, Applicants submit that the conclusions reached as to the sufficiency of the written description of the applications considered in the cases cited by the Office have little or no bearing on the instant case.

[10] In re Alton 37 U.S.P.Q.2d 1578 (CAFC 1996).

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number 23001487.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: September 27, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

New claims 123-130 have been added.